

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

ROY WILMOTH, JR.

PLAINTIFF

v.

CIVIL ACTION NO: 3:20-CV-120-NBB-RP

ALEX M. AZAR, II in his official capacity
as Secretary of the United States Department
of Health and Human Services

DEFENDANT

**WILMOTH’S OPPOSITION TO DEFENDANT’S
MOTION FOR SUMMARY JUDGMENT**

The Secretary’s motion for summary judgment should be denied.

The Secretary’s base claim to the unilateral power to abrogate the common law simply contradicts the direction of the Supreme Court. Moreover, as he has in other cases, the Secretary continues to conflate “precedential” and “collateral estoppel.” Those are distinct legal concepts. The Secretary has failed to meet his burden of showing, through statutes passed by Congress, that there is a “clearly expressed” Congressional intent to abrogate the common law. The Secretary is bound by collateral estoppel, the same as any litigant.

As to the elements of collateral estoppel, the Secretary’s claim that there is a material difference between, *e.g.*, July 2018 (when ALJ Petrylak found coverage) and June 2018 (when ALJ Bryant denied coverage) is without basis. The Secretary’s claim that there are “limits” when he could have appeared in any of the proceedings at issue is simply unsupported.

The Secretary’s motion should be denied.

I. DISCUSSION

A. Standard of Review

The Secretary’s claim that the court “may only scrutinize the record” (citing *Leggett v. Chater*, 67 F.3d 558, 564 (5th Cir. 1994)) is not correct. *See* Dkt. #58 at 7. As explained in Mr.

Wilmoth's own motion for summary judgment, because of the nature of collateral estoppel, a later issued decision that becomes final may have preclusive effect on an earlier issued, but non-final, decision. *See* Dkt. #60 at 3. Thus, independent of their inclusion in the administrative record, this Court may take notice of the "judicial fact" of the subsequent decisions of Cohn-Moros, *e.g.*, regardless of whether they were before the agency at the time the Bryant/Council decisions issued or thereafter. *See Opoka v. INS*, 94 F.3d 392, 394-95 (7th Cir. 1996) ("derelict" in duty to not consider later issued decision).

Further, in this case, the Secretary is attempting to rely on non-record information regarding the number of appeals pending in 2016 in support of his defense that he was not fully represented in Mr. Wilmoth's cases. *See* Dkt. #58 at 18 (citing non-record FEDERAL REGISTER publication by the Secretary). The Secretary should be consistent: either non-record "evidence" can be considered (in which case everything comes in) or it cannot (and the Secretary's reliance on his own FEDERAL REGISTER publications should be rejected).

B. The Secretary's Comments Regarding LCDs

The Secretary's brief includes a number of comments regarding LCDs. *See* Dkt. #58 at 4-5 and 9-10.

Local Coverage Determinations (LCDs) are policies developed by contractors to the Secretary that guide consideration at levels below reconsideration and reflect the contractors starting point for claim consideration. *See* 42 U.S.C. § 1395ff(f)(2)(B). On initial consideration and redetermination, the lower levels claim processing apparatus is bound by LCDs. However, on reconsideration by the Qualified Independent Contractor (QIC) and at the ALJ and Council level, LCDs are non-binding. *See* 42 C.F.R. § 405.968(b)(2) ("QICs are not bound by LCDs[.]"); 42 C.F.R. § 405.1062(a) ("ALJs ... and the Council are not bound by LCDs[.]"). Each of those

entities is free to not follow an LCD's recommendation but, if they choose not to follow it, the regulations require an explanation. The Secretary does not dispute this. *See* Dkt. #58 at 10, n. 3. Thus, LCDs control the initial processing of a claim but are merely something to consider at the QIC, ALJ, and Council levels. In the decisions on which collateral estoppel is based in this case, the ALJs considered the LCD, rejected it, and found that tumor treatment field therapy (TTFT) was medically reasonable and necessary for Mr. Wilmoth.

C. The Secretary Did Not Overcome the Presumption of Collateral Estoppel

As Mr. Wilmoth noted in his own motion for summary judgment, there is a presumption that collateral estoppel applies when agencies act in a "judicial capacity." *See* Dkt. #60 at 4-5. That presumption can only be overcome if the statute expresses a Congressional intent to abrogate the common law. *See Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) ("will apply except where a statutory purpose to the contrary is evident."); *U.S. v. Texas*, 507 U.S. 529, 539 (1993) ("statute must 'speak directly' to the question addressed by the common law"). If the statute is compatible with the pre-existing practice of the common law, the presumption is not overcome. *See BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994). Finally, the party asserting that the common law does not apply bears the burden of establishing that Congress intended a change. *See Green v. Block Machine Co.*, 490 U.S. 504, 521 (1989).

While *statutes* are required to overcome the presumption, the Secretary's brief focuses on his *regulations*. *See* Dkt. #58 at 8 ("The applicable Medicare regulations provide ..."). Regulations are not statutes and the Secretary's regulations indicate nothing about Congress' intent. Thus, *e.g.*, the Secretary's citation to 42 C.F.R. § 405.1062(b) for the proposition that ALJ decisions are not "precedential" and only apply to specific cases cannot overcome the presumption. *See* Dkt. #58 at 10. No amount of regulations can substitute for the lack of Congressional intent

to abrogate the common law of collateral estoppel.

The only statute the Secretary cites is 42 U.S.C. § 1395ff(d)(2)(B). *See* Dkt. #58 at 10.

That Statute provides:

DAB hearing procedure

In reviewing a decision on a hearing under this paragraph [*i.e.*, an ALJ decision], the Departmental Appeals Board¹ shall review the case *de novo*.

On its face, the Statute merely describes the common situation where a matter is reviewed *de novo* on appellate review. Of course, such review does not mean without regard to legal principles. Instead, it means that the matter is reviewed with no deference to the conclusions of the tribunal being reviewed. *See, e.g., In re: Deitz*, 760 F.3d 1028, 1043 (9th Cir. 2014) (“independent, with no deference given to the trial court’s conclusion.”).

Indeed, motions granting summary judgment are reviewed by appeals courts *de novo*, as are District Court rulings on issue preclusion. *See, e.g., Kariuki v. Tarango*, 709 F.3d 495, 501(summary judgment), 506 (collateral estoppel) (5th Cir. 2013). Thus, if *de novo* review were inconsistent with collateral estoppel, collateral estoppel could never apply. Obviously, that is erroneous.

Applying the Supreme Court’s standards, § 1395ff(d)(2)(B) does not “speak directly” to the issue of collateral estoppel (*Texas*, 507 U.S. at 534) or reflect that a “statutory purpose to the contrary is evident.” *Astoria*, 501 U.S. at 108. Further, like *de novo* review of the application of collateral estoppel on appeal in Circuit Courts, *de novo* Council review is compatible with the pre-existing practice of collateral estoppel, meaning the presumption is not overcome. *BFP*, 511 U.S. at 543 (phrase “compatible with pre-existing practice” not sufficient to overcome presumption).

None of the cases cited by the Secretary say otherwise. *See* Dkt. #58 at 10. *Porzecanski*

¹ The Medicare Appeals Council is also known as the Departmental Appeals Board.

v. Azar, 943 F.3d 472 (D.C. Cir. 2019) concerns the application of equitable estoppel and says nothing about collateral estoppel. Likewise, *Almy v. Sebelius*, 679 F.3d 297 (4th Cir. 2012) concerns the arbitrary and capricious standard across multiple cases and parties and, again, says nothing about collateral estoppel.

The Secretary did not bear his burden of overcoming the presumption of collateral estoppel and collateral estoppel applies to Medicare cases.

D. Alleged Interference With Implementation of the Medicare Statute

Independent of the presumption of collateral estoppel and the lack of Congressional intent to abrogate it, the Secretary alleges that collateral estoppel would interfere with his “discretion” to implement the Medicare statute. *See* Dkt. #58 at 11. Put simply, the Secretary has no discretion to abrogate the common law of collateral estoppel. That is a power reserved to Congress under the Constitution and the applicable cases from the Supreme Court.

Moreover, it is not correct to say that collateral estoppel would preclude individual adjudication of Medicare claims. Instead, each claim would continue to be considered on its individual merits. In the cases where collateral estoppel applies, it will properly preclude re-litigation of an issue previously decided with the appropriate result. Collateral estoppel does not preclude individual adjudication.

The Secretary’s citation to *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201 (5th Cir. 1980) is wide of the mark. *See* Dkt. #58 at 12. That case concerns something called the Provider Reimbursement Review Board (PRRB). The PRRB is not composed of ALJs. Instead, the PRRB is a five-member panel of “persons knowledgeable in the field of healthcare reimbursement” (42 C.F.R. § 405.1817) charged with reviewing accounting decisions of contractors regarding reimbursements to providers. In the words of the Seventh Circuit, the PRRB is comprised of

“minions” within the Department. *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987). Thus, the PRRB is not an instance of the Department acting in a “judicial capacity” and is irrelevant.

Almost all of the other cases cited by the Secretary are of the same ilk. That is, the Secretary repeatedly cites to cases where the Department is not acting in a judicial capacity or that have statements concerning either the arbitrary and capricious standard or equitable estoppel. None of those are relevant.

One case the Secretary cites merits some comment, mostly because the Secretary’s parenthetical is apt to mislead. The Secretary cites *Freeman v. U.S. Dep’t of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) for the proposition that “unappealed ALJ ruling could not estop the United States.” *See* Dkt. #58 at 13. There, the plaintiff sought to rely on ALJ decisions in “unrelated contest proceedings”, not involving the plaintiff, in which one ALJ determined that he had no jurisdiction to resolve an issue and another dismissed a case without prejudice as a result of a private party’s failure to comply with filing requirements. Relying on these decisions, the plaintiff contended that the DOI was collateral estopped because “the alignment in subject matter ... is as close as possible.” The district court rejected the argument on three grounds: 1) outside the context of collateral estoppel, decisions of ALJ are not binding on the DOI; 2) the ALJ decisions themselves demonstrated why they were “unappealed” and did not reflect an acquiescence by the DOI in the ALJ’s ruling; and 3) only mutual collateral estoppel applies against the United States, and the plaintiffs were not parties to the prior ALJ’ decisions.

The simple description of the case illustrates its inapplicability. Here, Mr. Wilmoth was a party to the prior ALJ decisions. Those decisions, in fact, determined his rights and the Secretary’s liability and the Secretary did not appeal them. Finally, Mr. Wilmoth is not asserting that the prior

decisions are “precedential” or bind the Secretary with regard to anyone other than Mr. Wilmoth himself.

E. Collateral Estoppel Does Not Interfere With “Presentment”

Respectfully, the Secretary’s comments regarding “presentment” appear to reflect confusion as to the relief sought in this case. In this case, Mr. Wilmoth seeks relief only as it regards his claim for coverage for the months of April-June 2018 and seeks no prospective relief. Moreover, as a technical matter, a case like this seeks “injunctive relief” not “damages” (*i.e.*, an injunction requiring the Secretary to provide coverage for the claims at issue). *See Bowen v. Massachusetts*, 487 U.S. 879, 893-901 (1988). Thus, the injunction sought has no relationship to “future” claims Mr. Wilmoth might submit.

The Secretary’s heavy reliance on *Porzecanski* is misplaced. *See* Dkt. #58 at 14-16. There, the plaintiff sought an injunction mandating coverage of any “future claims” the plaintiff might submit. *Id.* at 475 (“prospective equitable relief”). By contrast, Mr. Wilmoth seeks only retrospective relief. Further, the Secretary’s reading of the *Porzecanski* case is erroneous. In *Porzecanski*, the plaintiff both appealed the denial of a Medicare claim and sought declaratory and injunctive relief regarding any “future claims” he might submit. While reversing the denial of coverage for the claim at issue, the district court concluded that it could not issue declaratory and injunctive relief as to possible “future claims.” Only the denial of declaratory and injunctive relief as to “future claims” was the subject of appeal and the district court’s decision as to the claim actually denied was not at issue. *See Porzecanski*, 943 F.3d at 477-78. *Porzecanski* said nothing about collateral estoppel or preclusion with respect to the claim actually appealed to (and reversed by) the district court and only concerned the request for prospective relief.

Again, the Secretary simply has not shown that the presumption has been overcome or

cited a single case barring the application of collateral estoppel to Medicare cases.

F. The Elements of Collateral Estoppel Are Present In This Case

All the elements of collateral estoppel are present and bar the Secretary from denying Mr. Wilmoth's claim on the grounds that TTFT is not "medically reasonable and necessary" and a Medicare covered benefit for him.

1. The Issues in the Cases Are Identical

As Mr. Wilmoth showed in his own summary judgment papers, the identical issues of what TTFT was "medically reasonable and necessary" and a Medicare covered benefit for him were litigated in each of the cases on which collateral estoppel is based as well as the decision of ALJ Bryant being appealed in this case. *See* Dkt. #60 at 16-17.

The Secretary's claim that the issues are different because each decision relates to particular months does not stand up to even passing scrutiny. As noted, issues/facts are identical unless they are materially different with respect to the conclusions reached. *Id.* There is no material difference between, *e.g.*, June 2018 (when coverage was found) and April 2018 (when ALJ Bryant denied coverage). TTFT did not get any less effective, any less safe, or any less life-extending in the passage of those months and there certainly is no evidence to conclude that it did. Nor is there any change to Mr. Wilmoth's glioblastoma multiforme (GBM) diagnosis. There is unfortunately no cure.

The Secretary's reliance on *Applied Medical Resources Corp. v. United States Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006) (Dkt. #58 at 17) is particularly off-base. *Applied* is a patent case discussing reasonable royalties. Under Federal Circuit precedent (absent an established royalty), a reasonable royalty is based on the rate the parties would have accepted in a hypothetical negotiation taking place just before the infringement began. *Id.* at 1361 ("must relate

to the time the infringement occurred”). Thus, the reasonable royalty determined in one case for infringement beginning on one date cannot collaterally estop either party from arguing for a different reasonable royalty for separate acts of infringement beginning on a different date at issue in a later case.

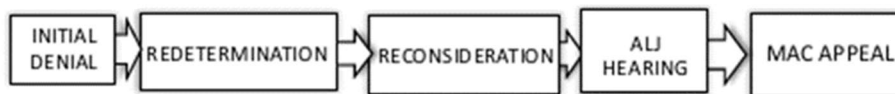
The identical issues of whether TTFT was “medically reasonable and necessary” and a “Medicare covered benefit” (as well as the various sub-issues) for Mr. Wilmoth was at stake in all the cases.

2. The Same Issue Was Actually Litigated

For the same reasons that the Secretary asserts that the issue are not identical, the Secretary asserts that the same issues were not litigated. Thus, for the same reasons, the Secretary is wrong. As demonstrated in Mr. Wilmoth’s own motion for summary judgment, Mr. Wilmoth was put to his burden of proof and ALJ decided the issue in each case on which collateral estoppel is based and in ALJ Bryant’s decision that is being appealed.

3. The Secretary Was Fully Represented/ Had A Full and Fair Opportunity to Litigate in the Prior Action

The Secretary’s claim that he has no opportunity to participate in proceedings below the ALJ level are irrelevant. *See* Dkt. #58 at 18. As described, Medicare has a five-level claim/appeal process. Below the ALJ level, the Secretary is not acting in a “judicial capacity” and those proceedings cannot give rise to collateral estoppel. At issue in this case are only those proceedings where the Secretary was acting in a judicial capacity that took place at the ALJ or Council level.



Likewise, the Secretary’s comments regarding proceedings involving unrepresented parties are irrelevant. *See* Dkt. #58 at 18. In the present case, it is undisputed that Mr. Wilmoth

was represented in each of the proceedings and that, as a result, the Secretary had all the rights of a litigant. *See* Dkt. #60 at 8-9. The Secretary simply chose not to take advantage of those opportunities and, instead, relied on the fact that Mr. Wilmoth still bore the burden of proof.

The Secretary further claims that “it is impracticable for the Secretary to litigate thousands of appeals annually filed by providers and represented beneficiaries.” *See* Dkt. #58 at 18 (citing a FEDERAL REGISTER publication of appeals pending in September 2016). Before addressing the Secretary’s factual claim, as Mr. Wilmoth has previously pointed out, this is irrelevant. Whatever the number of appeals, the Secretary is subject to collateral estoppel. *See U.S. v. Mendoza*, 464 U.S. 154, 159-60 (1984) (United States bound by collateral estoppel though it was a party to ~1/3 of all litigation in 1982).

With regard to the Secretary’s factual claim, no doubt the Court must have been curious why the Secretary was citing statistics from 2016 in a paper filed in October 2020. Indeed, why would the Secretary do that when he must have more recent statistics? The answer appears to be that 2015 and 2016 represented a unique “spike” in appeals caused by a very aggressive auditing program of hospital stays that resulted in the retroactive denial of hundreds of thousands of claims and, commensurately, hundreds of thousands of appeals by the hospitals. When the Secretary could not meet the statutory mandate to issue ALJ decisions within 90 days of appeal (and was instead projecting 4-5 years), the hospitals brought suit seeking a *writ of mandamus* in a case currently styled *American Hospital Association v. Azar*, Case No. 14-cv-851 (D.D.C.) (Boasberg, J.). There, the district court issued a *writ of mandamus* ordering the Secretary to reduce the backlog according to a schedule and to submit quarterly reports on the progress. *See* Dkt. #89. The most recent report was filed on September 24, 2020 and reflects ~201,000 pending appeals (rather than the 650,000 mentioned in the Secretary’s papers). *See* Exhibit A. Further, the writ requires the

Secretary to reduce the backlog by 50% by the end of FY21 and eliminate it by the end of FY22. While Mr. Wilmoth believes this all to be irrelevant, the number provided in the Secretary's briefing is apt to mislead the Court as to the true situation.

Further, as reflected in the Secretary's answers to Mr. Wilmoth's interrogatories, the actual number of represented beneficiary appeals in FY19 was **2,602**. As addressed below, these are appeals, not beneficiaries, and the beneficiary appeal count is but a fraction of that number. Moreover, the Secretary has published information indicating that in FY19, ~54% of ALJ requests were dismissed (*e.g.*, untimely filed, beneficiary passed away).² This implies that the actual number of hearings was ~1,197 (*i.e.*, 23 ALJ hearings a week). Indeed, this is the maximum number of represented beneficiary appeals the Secretary could participate in if he chose not to rely on the fact that the beneficiary bears the burden of proof (as he did in Mr. Wilmoth's cases). It strains credulity for the Secretary (with a budget of >\$750 billion) to argue that he cannot participate.

Moreover, Mr. Wilmoth notes the multiplication of the ALJ hearing count as a result of the Secretary's refusal to abide by collateral estoppel. The documents in this case alone reflect eight (8) ALJ decisions for the same treatment to the same beneficiary (whose GBM condition cannot be cured). Each beneficiary who needs ongoing treatment and is subject to the Secretary's policies is likely to have multiple claims each year resulting in multiple ALJ decisions. Thus, the Secretary should not be heard to complain that his own misguided policies have so multiplied the number of appeals that it would be unfair to apply collateral estoppel and the cycle must continue without end. Indeed, applying collateral estoppel would reduce the call on the Secretary's resources from repeated litigation of identical issues and that reduction is one of the purposes of collateral

² <https://www.hhs.gov/about/agencies/omha/about/current-workload/decision-statistics/index.html>

estoppel.

The Secretary's claim that he cannot appeal a decision of an ALJ if he chooses not to participate in the ALJ hearing is simply not true. *See* Dkt. #58 at 18. Pursuant to 42 C.F.R. § 405.1110, regardless of whether the Secretary chooses to appear or not, the Secretary can appeal a decision of the ALJ on so-called "own motion review." 42 C.F.R. § 405.1110(a) ("The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or any of its contractors may refer a case to the Council for it to consider[.]"). As provided, the Council can independently take up appeals or can receive "referrals" for appeals from CMS or any contractor. Thus, the Secretary's contentions in this regard are simply unsupported.

The Secretary had a full and fair opportunity to litigate.

G. Alleged Lack of Incentive

The Secretary contends that collateral estoppel should not apply because he lacked incentive to litigate Mr. Wilmoth's cases. *See* Dkt. #58 at 19. Of course, that exception to collateral estoppel depends on a disparity in the value of a first case as compared to the value of a second case. Here, the Secretary identifies no such disparity. Indeed, because each decision concerns three months of Mr. Wilmoth's TTFT coverage, each case is worth the exact same amount. Thus, there is no disparity and the Secretary had just as much incentive to litigate the cases on which collateral estoppel is based as he did in the case that is the subject of this appeal.

Instead of disparity, the Secretary appears to contend that he just did not care about the prior cases and, having forced Mr. Wilmoth to bear the expense and uncertainty of proving coverage, the Secretary would prefer it if Mr. Wilmoth repeated that cycle as long as he continues to live.

Avoiding that situation is the very reason for collateral estoppel.

H. Alleged Effect of “New” LCD/ “Changed” Circumstances”

The Secretary’s brief includes a number of comments regarding the possible effects of a “new” LCD that applies to claims submitted after September 1, 2019 as well as the possibility of “changed circumstances” in the future. *See* Dkt. #58 at 19-20. Respectfully, these are all irrelevant. At issue in this case is only Mr. Wilmoth’s claim for coverage for the months of April-June 2018, no prospective relief is sought. Whether collateral estoppel will apply in future cases will depend on the facts of those cases. “Changed circumstances” has always been a basis on which collateral estoppel may not apply and Mr. Wilmoth does not shy away from it. *See Montana v. U.S.*, 440 U.S. 147, 159 (1979) (“changes in facts essential to a judgment will render collateral estoppel inapplicable”). Thus, the Secretary’s comments in this regard are merely speculative.

I. Other Bases for Reversal

Mr. Wilmoth strongly believes that the Secretary’s decision denying coverage is not supported by substantial evidence and could be reversed on the merits. That is, there is simply overwhelming evidence that TTFT is safe and effective, not experimental, and medically reasonable and necessary for Mr. Wilmoth and there is *no* evidence to the contrary. TTFT has become the standard of care for GBM.

Nevertheless, because of the importance of the underlying issue of collateral estoppel and stopping endless battles over coverage that are costly and render inconsistent results, Mr. Wilmoth has decided to focus his grounds for relief on collateral estoppel. A coverage finding that relates to only a few months here or there and will not stop the ongoing drain on resources and worry associated with repeated litigation.

To the extent that it is relevant, the Secretary’s claim that the Administrative Procedure

Act does not apply to cases arising under 42 U.S.C. § 405(g) is not correct. *See* Dkt. #58 at 21 (citing *Estate of Morris v. Shalala*, 207 F.3d 744 (5th Cir. 2000)). Pursuant to § 405(g), the Secretary's "findings of fact" are evaluated under the "substantial evidence" standard. All other issues are evaluated under the standards of the APA. *See, e.g., Friedman v. Sebelius*, 686 F.3d 813, 826-27 (D.C. Cir. 2012) ("We therefore review the Secretary's decision to exclude the Appellants according to the arbitrary and capricious standard").

While Mr. Wilmoth battles brain cancer, the Secretary should not be allowed to draw him into an endless battle for coverage.

II. CONCLUSION

For the reasons set forth above, the Secretary's motion should be denied and Mr. Wilmoth's motion granted.

Dated: November 16, 2020.

Respectfully submitted

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document electronically, using the CM/ECF system, which will send notification of such filing to all parties of record in the above-captioned matter.

This, the 16th day of November 2020.

/s/ H. Ruston Comley
H. Ruston Comley